UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,239	03/01/2007	Klaske Van Norren	0470-060781	1258

28289 7590 04/29/2008

THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER	
NIEBAUER, RONALD T	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,239	VAN NORREN ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-36* is/are pending in the application.

4a) Of the above claim(s) *20-22,26,27 and 30-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,23-25,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II (claims 19-29) and the following species:

Guanosine equivalent (GTP increasing component) – GUANOSINE

Carbohydrate – GLUCOSE

(no other species were identified for the composition)

in the reply filed on 2/22/08 is acknowledged. The traversal is on the ground(s) that the claims are related in that they both recite a particular composition. Applicants argue that the search required for the examination of the method claims would encompass the search required for the composition claims. Regarding the species election, applicants argue that election of species is improper because a search directed to any of the species would clearly overlap.

The arguments have been fully considered but are not persuasive. As noted on the restriction requirement PCT Rule 13.2 defines “special technical features” as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” In the instant case, the inventive groups include compositions and methods of using compositions. The compositions are known (see Salwitz US 2003/0236217 as cited previously and see Alexander et al. (US 5,231,085) and Masor et al. (US 5,602,109) cited below), there is lack of unity a posteriori since the compositions do not define a contribution over the prior art. Regarding the actual search, the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries), the prior art applicable to one invention would not likely be applicable

to another invention, and the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Regarding the species search, each of the species are structurally distinct and require a different filed of search (i.e. searching different electronic resources or employing different search queries) and/or the prior art applicable to one species would not likely be applicable to another species. There is no evidence on record that the species are obvious variants.

The requirement is still deemed proper and is therefore made FINAL.

In the course of searching for the elected species any art that was found drawn to non-elected species is cited herein.

Claims 20-22,26-27,30-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/22/08. In particular claims 30-36 are drawn to a non-elected group and claims 20-22,26-27 are drawn to non-elected species.

Claims 1-18 have been cancelled.

Claims 19,23-25,28-29 are under consideration.

Specification

The disclosure is objected to because of the following informalities:

Section 608.01 VI of the MPEP states:

> Graphical illustrations, diagrammatic views, flowcharts, and diagrams in the descriptive portion of the specification do not come within the purview of 37 CFR 1.58(a), which permits tables, chemical and mathematical formulas in the specification in lieu of formal

> drawings. The examiner should object to such descriptive illustrations in the specification and request drawings in accordance with 37 CFR 1.81 when an application contains graphs, drawings, or flow charts in the specification.

In the instant case, the specification (pages 17-24,26 for example) includes graphical illustrations which are not to be in the specification.

Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

Applicant is reminded that the specification should include a section "brief description of the drawings" (see MPEP section 608.01(f)).

Appropriate correction is required.

The abstract of the disclosure is objected to because the abstract recites ranges of numbers that include '- 20-200 g/l', ' - 5-5000 mg/l', and - 45 to 97.95 wt.%'. The dash (i.e. -) before the numbers makes it appears as the quantities refer to negative numbers which would not make sense in the context of the instant invention.

Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19,23-25,28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites that the claims are drawn to methods of prevention specifically for mammals suffering from trauma. Claim 25 recites that the administration is prior to the occurrence of the trauma. As such, it is unclear if the patient population is or is not suffering from trauma. The recitation of claim 18 'suffering from trauma' implies that the patient population is suffering from trauma. However, claim 25 states that the administration is prior and it is known that preventative measures can be administered prior to the onset of an ailment. As such, the scope of the claims is unclear.

Claim 19 and dependent claims are drawn to methods of administering compositions where the composition comprises 'guanosine equivalents' and 'ribose equivalents'. The specification page 5 lines 19-23 provides a definition for 'guanosine equivalents'. However, the scope of 'guanosine equivalents' remains unclear. In particular the definition recites that 'precursors of guanosine' are encompassed in the definition. The term 'precursors of guanosine' is unclear. In particular it is unclear if any compound involved in a chemical synthesis or a biological pathway including guanosine would be considered a precursor.

Further, page 5 lines 24-25 states that the term 'ribose equivalents' is defined in accordance with the definitions provided above for guanosine equivalents and folic acid equivalents. As such, the scope of "ribose equivalents" is unclear. In particular it could be interpreted that based on page 5 lines 24-25 that the definition of 'ribose equivalents' is to be interpreted the same as 'guanosine equivalents'.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19,23-25,28-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*,

> 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the

claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to a method of preventing multiple organ dysfunction comprising administering guanosine equivalents or ribose equivalents for example.

(1) Level of skill and knowledge in the art:

The level of skill in the art is high.

(2) Partial structure:

Although the claims are unclear (see 112 2nd) the claims are given the broadest reasonable interpretation (see MPEP section 2111). In particular page 5 line 19-28 recite definitions of guanosine equivalents and ribose equivalents. In particular the definition recites that 'precursors of guanosine' are encompassed in the definition. As such, any compound involved in a chemical synthesis or a biological pathway including guanosine would be considered a precursor. It is noted that the precursors are not required to share any structural features with guanosine. Hence, there is substantial variability in the genus.

However, there are few examples of guanosine equivalents. Page 5 recites guanosine salts and guanosine esters. The examples (examples 1-7) recite guanosine and GTP.

Since there are a substantial variety of equivalents possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

Claim 19 recites that the guanosine equivalents are a liver GTP increasing component. Page 5 line 21 states that precursors can liberate guanosine. However, there is no disclosed correlation between structure and function. In particular one of skill in the art would not recognize the structure of precursors that liberate guanosine. In particular, the common attributes or characteristics that identify liver GTP increasing components and precursors that can liberate guanosine have not been set forth. No common sequence or common core is taught for the equivalents. No guidance is provided as to what are the key structural features necessary to act as a liver GTP increasing component.

(5) Method of making the claimed invention:

The specification (exampled 1-7) describes compositions with guanosine and GTP, however the specification fail to describe a representative number of equivalents.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 19,23-25,28-29 is/are broad and generic, with respect to all possible guanosine equivalents and ribose equivalents encompassed by the claims. The possible structural variations are many. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the equivalents beyond those equivalents specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of equivalents identified in the specification tables

and/or examples, the specification does not provide sufficient descriptive support for the myriad of equivalents embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 19,23-25,28-29 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention:

The claims are drawn to methods of preventing multiple organ dysfunction.

Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "therapeutic" or "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes).

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the art in preventing multiple organ dysfunction is unpredictable. Applicants own specification states that 'no effective treatments have been developed so far' (page 1 lines 22-23).

Seely et al. (Crit Care Med v28 2000 pages 2193-2200) teach that multiple organ dysfunction represents the most common cause of death in the intensive care unit (first paragraph page 2193). Seely teach that multiple organ dysfunction treatment is largely supportive (i.e. not preventative) (first paragraph page 2193). Seely teach that numerous clinical studies of therapy for patients with multiple organ dysfunction have been universally disappointing (first paragraph page 2193). Seely conclude (page 2198 section 'conclusions') that effective immunomodulation of a patient with multiple organ dysfunction represents the most difficult challenge facing critical care medicine.

Ciesla et al. (Arch Surg v140 May 2005 pages 432-440) teach that multiple organ failure remains a major source of morbidity and is the leading cause of in-hospital mortality despite more than 25 years of intense investigation (first sentence page 432).

Johnson et al. (Canadian Journal of Anesthesia v48 2001 pages 502-509) teach that therapy directed to prevent or improve multiple organ dysfunction has not dramatically altered outcomes (last line of 3rd paragraph 'results section' page 502).

Taken together, the state of the art in preventing multiple organ dysfunction is unpredictable.

(5) The relative skill of those in the art:

The level of skill in the art is high.

(2) The breadth of the claims

Although the claims are unclear (see 112 2nd) since the claims are drawn to administration prior to the occurrence of trauma the claims are interpreted as being open to numerous causes of multiple organ dysfunction including trauma, pancreatitis, burns, shock, infection, aspiration, etc. (compare Steely et al. page 2193 last paragraph). Trauma includes such things as gunshot wounds and stabbings. It is noted that the claims are open to any and all degrees of severity of the trauma, for example multiple gunshot wounds.

As discussed above the term "prevent" is an absolute definition which means to stop from occurring. As such, the claims are drawn to prevention at any point in time in the future.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification provides examples of rat studies in which pre-operative supplementation was investigated (examples 8-9). The examples show the effects of supplementation (page 17-24) on various parameters such as intestinal permeability, bacterial translocation, and lung inflammation. The specification provides examples in which the effects of supplements for a cell line was investigated (page 25-26).

However, the specification does not provide examples of the treatment nor the prevention of any and all types of multiple organ dysfunction. In particular the examples are not drawn to mammals suffering from trauma of any type let alone cases including situations such as multiple gunshot wounds. Further, the specification does not provide guidance on how the examples of intestinal permeability, bacterial translocation, and lung inflammation correlate to prevention of multiple organ dysfunction as a result of trauma.

One of skill in the art would not equate the effects of supplementation (page 17-24) with the ability to prevent multiple organ dysfunction. One would not extrapolate results from mammals that are not suffering from trauma to mammals that are suffering from trauma. Further, the specification does not provide any correlation between guanosine equivalents and carbohydrates and their ability to prevent multiple organ dysfunction. Although guanosine and carbohydrates may effect the metabolism of patients one would not equate altered metabolism with prevention of multiple organ dysfunction. Such guidance is necessary because the prior art cited above teach that the prevention of multiple organ dysfunction is unpredictable. As stated above, Seely et al. (Crit Care Med v28 2000 pages 2193-2200) teach that multiple organ dysfunction represents the most common cause of death in the intensive care unit (first paragraph page 2193). Seely teach that multiple organ dysfunction treatment is largely supportive (i.e. not

preventative) (first paragraph page 2193). Seely teach that numerous clinical studies of therapy for patients with multiple organ dysfunction have been universally disappointing (first paragraph page 2193). Seely conclude (page 2198 section 'conclusions') that effective immunomodulation of a patient with multiple organ dysfunction represents the most difficult challenge facing critical care medicine.

Accordingly one would be burdened with undue experimentation to determine if the compositions of the current invention could be used in methods of prevention.

(8) The quantity of experimentation necessary:

Experimentation is required in numerous areas particularly related to how to use the method and determination if it would be useful for the prevention of multiple organ dysfunction. Considering the state of the art as discussed by the references above, particularly with regards to the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19,23-25,28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexander et al. (US 5,231,085).

Alexander teach the administration of compositions (examples 2 and 3). Specifically the compositions are taught to be suitable for patients who suffer from post-surgical trauma or trauma (column 5 line 28-36) as recited in claims 19,23-24 of the instant invention. In example 2 (column 6 line 63-64) the patients have experienced trauma or major general surgery and in example 3 (column 9 lines 3-4) the patients have undergone major operation. In example 2, the patients are administered composition A (column 7 line 46-47). Composition A is disclosed in column 6. The amount of composition A was calculated based on energy expenditure (column 7 line 51-55). Alexander teach that the daily amount is usually 1000-2000 kcal/day (column 4 line 10-12). Composition A includes 197.6 g of carbohydrate (in 1500ml so the concentration is 132 g/l) and 0.56-0.77g guanine (which is interpreted as a 'guanosine equivalent'). Based on the usual 1000-2000 kcal/day (column 4 line 10-12) the amounts of carbohydrate and guanosine equivalent meet the claimed limitations recited in claim 19 for example. Alexander teach enteral administration and liquid compositions (column 9 line 10-11 and column 3 line 56-62 for example) thus meeting the limitations of claims 28-29 of the instant invention.

It is noted that the current claim is drawn to a method of prevention. Since a method of prevention is used on a patient population prior to the onset of the ailment/disorder, any patient population is available for preventative administrations. Alexander teach the active method steps thus meeting the claim limitations inherently.

Although the claims are unclear (see 112 2nd) since the claims are drawn to administration prior to the occurrence of trauma the claims are interpreted as being open to administration to any patient population at any time.

Although the claims are unclear (see 112 2nd) the claims are given the broadest reasonable interpretation (see MPEP section 2111) such that the composition of Alexander meet the claimed limitations.

Claims 19,23-25,28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Masor et al. (US 5,602,109).

Masor teach (claim 1) the administration of compositions comprising 60 to 110 g/l of carbohydrate and at least 70 mg/l of guanosine. Although Masot does not expressly recite the volumes administered, using typical volumes the amounts fall within the ranges recited in claim 19 of the instant invention. Masor teach that glucose is a specific example of a carbohydrate of the invention (column 5 line 40). Masor teach the composition as a liquid (claim 2 for example) and teach enteral administration (column 5 line 40) thus meeting the limitations of claims 28-29 of the instant invention.

It is noted that the current claim is drawn to a method of prevention. Since a method of prevention is used on a patient population prior to the onset of the ailment/disorder, any patient population is available for preventative administrations. Masor teach the active method steps thus meeting the claim limitations inherantly.

Although the claims are unclear (see 112 2nd) since the claims are drawn to administration prior to the occurrence of trauma the claims are interpreted as being open to administration to any patient population at any time.

Although the claims are unclear (see 112 2nd) the claims are given the broadest reasonable interpretation (see MPEP section 2111) such that the composition of Masor meet the claimed limitations.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. EP 0302807 as cited in the IDS specifically example VII table X page 20 remains of record. Any rejection using EP 0302807 would be repetitive of rejections above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald T Niebauer/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654